# UNITED STATES BANKRUPTCY COURT DISTRICT OF DELAWARE

IN RE: . Case No. 01-1139 (JKF)

W.R. GRACE & CO.,

et al., USX Tower - 54th Floor

600 Grant Street

Pittsburgh, PA 15219

Debtors. .

March 26, 2008

. . . . . . . . . . . . 8:38 a.m.

TRANSCRIPT OF TRIAL
BEFORE HONORABLE JUDITH K. FITZGERALD
UNITED STATES BANKRUPTCY COURT JUDGE

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THE COURT: Good morning, please be seated. This is 1 the continuation of the personal injury estimation trial in 2 W.R. Grace, 01-1139. Participants by phone, Alex Mueller, 31 James Reiger, Matt Doheny, Theodore Tacconelli, Michael Davis, Francis Monaco, Matthew Russell, Shayne Spencer, Lewis Kruger, James Wehner, Elihu Inselbuch, Walter Slocumbe, Leslie Kelleher, Peter Lockwood, Bernard Bailor, Guy Baron, Ari Berman, Michael Lastowski, Janet Baer, Marti Murray, Jason Solganick, Debra Felder, Nathan Soucy, Natalie Ramsey, Terrence Edwards, Daniel Silver, Edward Westbrook, Kim Christensen, William Wagner, Andrew Hain, Andrew Craig, David Parsons, Ken Pasquale, Martin Dies, Peter Shawn, Jonathan Brownstein, Scott 13∥ Baena, Darrell Scott, Jay Sakalo, David Turetsky, Timothy 14 Cairns, Elizabeth Devine, Michael Scott, John Phillips, Daniel Speights, Matthew Kramer, Christina Skubic, Mark Hurford, Beau Harbour, Jeanna Rickards, Robert Guttmann, Christina Kang, Catherine Chen, Alan Madian, David Beane, John Greene, Matthew 17 Daiker, John Ku, Andrew Chan, William Corcoran, Robert Horkovich. 19 I'll take entries in Court for the court reporter, 20 21 Good morning. MR. BERNICK: Good morning, Your Honor, David Bernick 22

23 for Grace.

MR. McMILLAN: Good morning, Your Honor, Scott 25 McMillan for Grace.

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MS. AHERN: Good morning, Ellen Ahern for Grace. 1 2 MS. HARDING: Barbara Harding for Grace. MR. FINCH: Nathan Finch for the ACC, Your Honor. 3 4 MR. INSELBUCH: Elihu Inselbuch for the ACC. 5 MR. MULLADY: Good morning, Your Honor, Raymond Mullady for the FCR. 61 7 MR. ANSBRO: John Ansbro for the FCR. 8 MR. KIM: Anthony Kim for the FCR. 9 MS. KRIEGER: Good morning, Your Honor, Arlene 10 | Krieger for the Unsecured Creditors. MR. KRAMER: Good morning, Your Honor, Matt Kramer 11 12 for the PD Committee. MR. HOROWITZ: Good morning, Your Honor, Greg 13 14 Horowitz for the Official Equity Committee. MR. FRANKEL: Good morning, Your Honor, Roger Frankel 15 16 for the FCR. THE COURT: Give me one second, Mr. Bernick, please. 17 (Pause) 18 THE COURT: Folks, I had my staff up this morning. 19 20 Mr. Finch, did you explain to people about the microphones by any chance? 21 22| MR. FINCH: Not yet, Your Honor, THE COURT: Okay. Looking at the microphone issue 23 24 and your conferences, it turns out in trying to get the system 25 fixed so that we don't have the feedback, apparently what's

happened is that the microphones are now very sensitive, so in order to have conferences that are not picked up, you have to do one of two things; either hold the push button, that little button that makes the light go off the entire time that you're doing your conference, which is virtually impossible, or it works if you simply turn the microphones, all of them, at your table around, so that they face the opposite direction while you're doing your conference because they're conical mikes and as a result they will not pick up the sound while you're doing the conference. We tested it this morning and the other table can't hear while you're talking, while you turn the microphones around. So, I think that will protect all of you. If you will 13 take that effort this morning.

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MR. BERNICK: I appreciate that. Your Honor, it 15∥ reminds me many, many years ago we tried the San Juan DuPont Plaza fire case in San Juan, Puerto Rico and there were so many defendants in the case that they built a special jury box that isolated the jury so that you didn't have to have all the lawyers going up for a side conference. They put microphones on all the tables and you had to activate them. So, what would happen, in the middle of the testimony somebody in the vast hoards of the defense lawyers would want to object, so they would pull the microphone forward and activate it, but of course, when they did it, the swizzle stick would squeak and so there's this squeak objection. But this is -- I appreciate

this is a much better system under any set of circumstances. think we'll just have to deal with it.

THE COURT: All right.

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MR. BERNICK: Your Honor, in terms of what we have today, we obviously have Dr. Anderson's testimony, which will take the bulk of the day and we'll begin with that. We had planned on offering into evidence a series of summaries. are summaries of deposition testimony, picking up on Your 9 Honor's suggestion to that effect, as well as case law that 10 says that that's very appropriate.

We've had some difficulty in trying to reach resolution with the ACC and the FCR concerning the use of these 13∥ summaries and mostly it's general issues that have been raised concerning whether it's appropriate to have these kind of 15 summaries.

What I would propose and what I've already told Mr. Mullady and Mr. Finch, is that it might be worthwhile if Your Honor were to simply glance through these at some point during the day and then really give us feedback on whether this is useful. If it's not useful and you'd rather just have the depositions read in, we've got the designations and the counters and all the rest of that, we can do it that way. would very, very much prefer to do it this way because it's much more meaningful, but if Your Honor doesn't find it to be useful, it's not worth going to the step then of arguing the

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issues about admissibility. We'd be prepared to defer to whatever it is that Your Honor finds to be most appropriate.

So, these are 1006 summaries, based upon the deposition testimony. I don't believe that there's really an 5∥ issue about whether the excerpts that we are summarizing are appropriately excerpted, there are issues about whether the process is appropriate; that is, whether you can do this. They 8 would also like to have their counter designations in some 9 fashion included and they're not.

And then there's a specific issue with respect to 11 invocation of the Fifth Amendment which we can take up as well. 12 So, what I suggest, we just tender these to the Court. Your 13∥ Honor can flip through and let us know. If it is something 14 that you believe would be appropriate, then we can take up the 15∥ issue later on this afternoon of the objections that have been 16 | lodged specifically to these and proceed accordingly, and that 17 would take some time this afternoon.

THE COURT: All right. Let me make sure I 19 understand. What you're going to give me is a summary of a deposition; that is, an excerpt from the deposition that is 21 like a question and answer by line that the debtors intend to use but does not have the counter designations from the other side.

> MR. BERNICK: Yes.

THE COURT: And the purpose is simply to see whether

this is an appropriate process. If it is, then the other side wants to do the same process?

MR. FINCH: Correct, Your Honor.

MR. BERNICK: And if you could just flip on the ELMO very briefly, I'll just give you an example.

THE COURT: All right.

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MR. BERNICK: But the idea is that there are excerpts, they're also listed by topics and we tried to make the topics non-argumentative so that they are simply topics. Obviously, the summary itself are our summary, it's not their summary, is there a -- there we go. And if they want to make their own summaries and submit their own summaries, we wouldn't 13 | have a problem with that. We don't think it's appropriate, if we're tendering our summary, that we have to include their designations because it's our summary. So, they can do their own summary if they want, we have no issue with that if they want to put that in.

But Your Honor can see that with respect to Ray Harron, we have the exposure topic, testimony in prior cases, testimony in this case. This presents the Fifth Amendment issue which we're happy to argue, but that's essentially how they work, is a topic, a Q&A and then in the prior case, and a Q&A in this case. If we took another example, here you have -this is Dr. Gaziano's testimony regarding diagnostic practices. 25 Here are the different topics and then here are the quotes from

the deposition, including the cites.

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So, we think it's a much more useful way of digesting a lot of information that otherwise would take a lot of time to present to the Court. We have case law to support the proposition that this is totally appropriate. But, again, our quiding principle in the first instance is whether Your Honor would find it to be more useful than simply taking three hours to play all these depositions and encounters.

THE COURT: All right. And then the question then is, are all of the summaries by Q&A, in Q&A format, they are not somebody's summary of the witness' testimony, they are actually Q&As?

In some cases, they're in Q&As and in MR. BERNICK: 14 some cases -- you can see right here, just the statement does 15∥ not quote, exclude, so it is an effort to capture the essence 16 of the words and we are prepared to demonstrate in each case, that that is the appropriate -- no objection has been made that says, well, you've got that wrong. They've said that they're too busy doing other things. I don't want to get into that. They've been coming here with 14 --

MR. MULLADY: That's not right, Your Honor.

MR. BERNICK: -- well, we've got the e-mails, 14 lawyers everyday sitting here in court and they can't work on They're giving us their own designations for their case 25∥ that hasn't even started. I won't get into that, the point is

that there's no issue that's been raised concerning the accuracy of any of the excerpts that have been made.

But, again, we can argue about that this afternoon. The threshold issue is whether this is more useful to the Court than reading the depositions. So, if we have to read the depositions, we will read all the depositions. It'll take three and a half or four hours, we're basically talking about pushing back the closing of our case a day.

THE COURT: All right.

MR. MULLADY: May I be heard, Your Honor?

THE COURT: Yes, sir.

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MR. MULLADY: I'd be happy to fully address this issue this afternoon, Your Honor. I didn't want to take the Court's time or delay the witness presentation. But I do think it's important for the Court to know that we made a proposal last night to Grace which we think satisfies both our concern about these being improper Rule 1006 summaries because they attempt to summarize deposition that has already been admitted into evidence in some cases and in other cases, is the subject of fully designated deposition testimony which has not been offered, where our counter designations are there.

But, the proposal we made was, if the purpose of this is to assist the Court and to streamline Your Honor's review and to make it easier for you to get through all of this, these can be demonstrative exhibits which can be offered as

demonstratives, not in evidence under Rule 1006 and then the full deposition designations that both sides spent a lot of time this weekend working on, including counter designations and a discussion about whether exhibits should go in, all of that should just go into evidence and then Your Honor can have the demonstratives to assist you in identifying what the debtor feels is important testimony for you to review and we could do the same thing when we get to our case.

THE COURT: Doesn't that work?

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MR. BERNICK: No. It doesn't work for two reasons. First of all, they've made a lot of counter designations. We gave them this stuff Saturday night, so the idea that they didn't know this was happening is ridiculous.

Secondly, with respect to the demonstratives, the demonstratives will not be part of the record. And what will be part of the record is the depositions. And then what we have to do is actually read the deposition testimony into the record. So, we're talking about three and a half or four hours.

THE COURT: Well, can't I accept the written depositions without having them read into the record? I mean, I can read them myself.

MR. BERNICK: Well, but --

MR. MULLADY: Of course you can.

MR. BERNICK: Excuse me. The summary will not be --

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Your Honor, you would have to incorporate -- if you were to write any opinion, you'd have to incorporate, you'd have to go back and actually read this stuff. The depositions --

THE COURT: I would expect to read this stuff.

MR. BERNICK: Yes, but if we don't play it -- Your Honor expressed a concern that if we don't play it, we're postponing issues of admissibility and we don't really know what's there. This way you have only those portions that we want to use. And if there are issues about admissibility, they get raised with respect to a handful of summaries. summaries are not voluminous and we can go through and deal with the objections, if there are objections, as to the admissibility of the evidence very, very quickly. And Your 14 $\parallel$  Honor then knows exactly what is of relevance in those 15 depositions. Otherwise, I believe that what Your Honor has 16 observed is that the problem is that you will then get, and 17∥ we'll have the same kind of issue with respect to the Grace depositions as well, a bunch of transcripts and nobody really knows what is in and what is out, and they are characterized differently and the issue of what's admissible and not has been deferred. The whole idea of doing these summaries is precisely to focus on the what counts. And, again, if they want to do their own, we have no issue with that.

Now, I said what's useful to the Court is our benchmark because if Your Honor doesn't find it useful, then

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we'll go back the other way. But, as a matter of what's admissible under the rules, this is plainly admissible under the rules. 1006 doesn't say you can't summarize deposition testimony or any other kind of evidence. Your Honor actually suggested that we do down this road on January the 23rd in the course of a hearing and we have since looked into the case law and there's case law squarely on point that says you can do So, when they came back and said last night, after they didn't have time to deal with this issue on a substantive basis, and said, well, why don't you just take demonstratives. That's another way of saying, no, you can't get it into evidence. And if that's their position, it's not really a compromise at all, we could always have it tendered in as a demonstrative, we didn't need their permission to do that. if this is going to happen as a piece of evidence, let them come back and say as a piece of evidence, you know, we will do this, if you will permit us to do our own summaries of counter designations, no quarrel with that. But the idea that because they're too busy, we can't tender on a totally legitimate basis, the essence of these depositions which will otherwise take hours and then deal with the relevance issues, I think is wrong and I want these summaries to be part of the record for all purposes in the case. And I think we're entitled to make that proffer.

THE COURT: Okay. I will take a look over the lunch

recess at whether or not what has been submitted is helpful. have not ever looked at the concept of a summary of deposition testimony. I just have never been presented with that issue. Frankly, if it's helpful, it's probably a great way to proceed 5∥ because there are numerous depositions in the case and if it 6 works, and if it's admissible, it would probably be a good way to proceed. Whether it is admissible, I don't know, and have 8∥ you done briefs on this issue, because if you have, I haven't seen them?

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MR. MULLADY: Well, Your Honor -- we haven't briefed 11 it, Your Honor, but we did last night, when I communicated with 12∥Mr. Bernick's team about this issue, we had an ALR citation in 13 front of us and cases from a number of circuits saying that 14 these are not admissible for purposes of summarizing deposition 15∥ testimony. And we'll have those authorities this afternoon, if 16 Your Honor would like to hear about them.

I want to make one other point, which is that 18 yesterday, Mr. Bernick offered into evidence, without 19∥ objection, with our express agreement, certain summaries that we did not find objectionable. And so, the notion that we -you know, we've been too busy to focus on this, or give attention to the request by the debtors, you know, is just a false charge.

And, Your Honor, I really wish we could elevate the 25 | level of the discourse in this courtroom to what is actually

occurring in these discussions with counsel, which have been very amicable. I had two very nice conversations last night with Mr. Bernick's team, he was not on the phone, I understand he was preparing Dr. Anderson, as I was trying to, but the point is, we did work with them to try to resolve this issue. We're not too busy for the matters that Mr. Bernick would like to bring before the Court. We've never been so and it's unfair for him to say that repeatedly. Thank you.

THE COURT: Okay.

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MR. BERNICK: Well, you know, Your Honor, I have to say that Mr. Mullady is absolutely misrepresenting the tone of the dialogue. The tone of the dialogue, and we have the e-mails and we can show it to the Court --

THE COURT: It's okay.

MR. BERNICK: -- is that they didn't want to talk 16 with us.

THE COURT: Folks. Gentlemen, it's fine. look at these over the lunch recess and make a determination as to whether, first of all it's helpful. I am not over the lunch recess going to do legal research on this issue. I am trying in this case to get four opinions out in the next two weeks and as a result, what I'm going to be doing, in addition to looking at this, is working with my two law clerks to try to get two of those opinions out, hopefully tomorrow, if I can. So, that is 25 | how I'm going to be spending my lunch recess in this case, not

working on this issue. I already have plans for what I'm doing over the lunch hour today. So, that's -- I will take a look at this to see whether it's helpful

With respect to a brief, if you can give me some citations for this afternoon, I will be happy to hear argument if you can do it this afternoon, but I am not going to be looking at those citations today, I can assure you. Between 8 now and when you're back before me for the next round of trial issues, I will give you a ruling, but I will not be doing it today, I guarantee. It will not be today.

MR. BERNICK: Okay. Well, then Your Honor, we will 12 give you the citations right now. Which is 304 --

THE COURT: I'm sorry, 304 --

MR. BERNICK: F.3rd. 237.

THE COURT: All right.

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MR. BERNICK: It's a Third Circuit decision, 2002, <u>United States v. Velasquez</u> and Headnotes 1 and 2 deal with this issue. There are other citations that we can supply.

Your Honor, this is -- after today, there are only two pieces of evidence left in our case, which is Dr. Florence on Monday, and this.

THE COURT: Yes.

MR. BERNICK: So, if we can't do it this way, we are 24 | talking really about probably using Monday in order to deal 25∥ with this issue and then call Dr. Florence on Tuesday, in which

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case we're not talking about pushing our resting back to Tuesday afternoon. If that's the way this goes, that's fine, but this did not have to occur. We raised this over the weekend, on Saturday, and we've repeatedly asked for the opportunity to meet and confer and we were told repeatedly that they were not available for this.

And at the same time, we are getting deposition designations as part of their case. They've still got 12 people here today, sitting here in court, instead of working on this. And this, I don't think, is the way to proceed here. we're going to have to finish our case, we need their resources available to respond.

MR. MULLADY: We've responded.

THE COURT: Okay. I will, as I said, take a look at this. Mr. Mullady, do you have a cite because if so I'll have law clerks right now who are probably listening in and if not I'm going to take a two second recess to give them the cites.

MR. MULLADY: I do not, Your Honor. They're back at our work room. I can have them for you in half an hour.

THE COURT: Fine. Get somebody to do them and as soon as you have the cites, I will get a law clerk to take a look at these cases.

MR. MULLADY: Yes, ma'am.

THE COURT: One second please. And maybe I can give 25∥ you a ruling later. All right. There's one binder or two

binders?

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MR. BERNICK: There's two binders; one for the Court and one for Your Honor. And they're just behind each of the individual tabs.

THE COURT: They're duplicates?

They're duplicates, that's correct. MR. BERNICK:

THE COURT: Okay. Thank you. Jan, let me have the other one so I can give it to Mona, please. Thank you.

MR. BERNICK: The other matter that we had scheduled to be taken up this afternoon is the arguments on the Rule 408 issue.

THE COURT: Yes.

MR. BERNICK: We would like to do that. It's the same kind of problem. Pertains to our witness on Monday. 15∥We're going to be prepared to do that, I believe we'll be able 16∥ to finish Dr. Anderson in time to be able to do these things, although the 106 issue is -- well, I think we can probably get it done. So, that's our goal today and then we would do Dr. Anderson on Monday and we would rest.

THE COURT: Dr. Florence?

MR. BERNICK: Not Anderson. Dr. Anderson today, Dr. Florence on Monday, and then rest.

THE COURT: Yes.

MR. BERNICK: So, with that, unless there's other 25 business the Court would like to take up, we'll call Dr.

Anderson to the stand.

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THE COURT: Anything before Dr. Anderson? All right. Dr. Anderson.

MR. BERNICK: Oh, one last -- I'm sorry. ZAI, we should also talk about this afternoon. We got a boat trip and a vacation that are taking two people who want to be part of the property damage argument out on May and on June, so we, for some reason can't seem to get people to show up for the ZAI hearing. This is on the issue of the bar date.

> THE COURT: Oh.

MR. BERNICK: I got a conflict because I have to be in court for an argument that's been scheduled for three months on April 22, payable on April 21. On April 22, Your Honor 14 can't do it, so you gave us a date at the end of May. Mr. 15 | Baena has got a vacation planned. You then gave us another date for the early part of June, Mr. Westbrook has got a boat trip and this thing is really being --

> THE COURT: Why couldn't I do it on April 22? MR. BERNICK: I don't know.

THE COURT: I thought it was just April 21 because you were here on the omnibus?

MS. BAER: Your Honor, we asked about April 22 and 23 you indicated that you have, I think, the Federal Mogul -- not Federal Moqul, Flintkote disclosure statement hearing in 25 Delaware, and so it was a very full day.

THE COURT: Okay. Just --1 MR. BERNICK: Yes. That, I can tell Your Honor will 2 be -- I'm going to argue part of that, if not -- well --3 THE COURT: How long is that going to take? 4 MR. BERNICK: I don't think -- I mean, that really 5 has got a couple issues, it's not a dink, dink, dink, dink, through the disclosure statement. There are legal issues that I think are going to be raised. 81 9 THE COURT: Yes. MR. BERNICK: So, I don't think that that's going to 10 take all that long. How much time did you have that down for? THE COURT: I don't think I have access to my 12 Delaware calendar here. Let me see. 13 II MR. BERNICK: I just wanted to flag it to Your Honor 14 so that --15| 16 THE COURT: What I know is, that I have to leave court that day by 1:30 in order to catch the only flight out 17

that I was able to get home that day. So --

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MR. BERNICK: Flintkote is set for nine o'clock or --THE COURT: Pardon me just a minute.

(Pause)

It looks like Flintkote is scheduled at THE COURT: 9:30 and I think the parties told me that it was going to take a about two hours to argue, is that a good estimate?

MR. BERNICK: I don't think it should take that long,

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but I mean, I know that our argument will not last that long. There are --

THE COURT: All right. So, if I schedule -- and how long will ZAI take?

MR. BERNICK: I think that ZAI will probably take an -- well, given the way things usually go, it'll take an hour and a half. But the -- Your Honor has been through all the stuff before on ZAI, so I think actually it might be -- I know that we can arrange to have our side available on Flintkote earlier in the morning, if we could start at nine or something like that.

THE COURT: I've got things starting at 8:30 and there are rules -- Chapter 13 issues -- Owens. There's something scheduled in ABB or in Combustion, I think there are 15 two things scheduled in Owens. I don't think we're going to get started on Flintkote before 9:30.

> MR. BERNICK: I think I can get rid of that one. THE COURT: Okay. Well --

MR. BERNICK: I don't know what the schedule may be.

THE COURT: Okay. I just don't think we're going to get started on Flintkote before 9:30. So, if we say until 11:30 on Flintkote, and I put ZAI on at 11:30, but I have to leave at 1:30. So, I can give you --

MR. BERNICK: I think that that should -- oh, that 25∥ would be -- well, how about if we raise that with Baena and

Westbrook and who is the other guy, Scott?

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THE COURT: Mr. Baena and Mr. Westbrook, are you on the phone? All right.

MR. BERNICK: I think somebody from Mr. Baena's office is here.

THE COURT: That's the debtor's cite. The ACC or FCR is coming back later with the cite. If you can turn your thing on, as soon they do it, I'll let you know.

MR. BERNICK: That's fine.

MR. KRAMER: Your Honor, Matt Kramer, I'll check with them during the next break.

THE COURT: All right.

MR. KRAMER: And see if that works for them.

THE COURT: Okay. Thank you.

MR. BERNICK: And then we'll check with Scott --

MS. HARDING; Darrell Scott.

MR. BERNICK: Darrell Scott, yes.

THE COURT: Okay. Well, temporarily, I'll put ZAI on at 11:30 on April 22nd then. And Ms. Baer can do the notice if everybody agrees and if not, will you let me know?

MS. BAER: I will.

THE COURT: Okay.

MR. BERNICK: These are our Rule 1006 cases, Your Honor. Copies. We've given a copy to the other side.

THE COURT: Oh. I'm not sure Mona has her speaker on

### Anderson - Direct

Mona, if you have your speaker on, can you come back in, there are copies of cases here for you?

MR. BERNICK: With that, I think we're prepared to call Dr. Anderson to the stand, if Your Honor would like to proceed.

THE COURT: All right. Dr. Anderson.

THE CLERK: Please stand and raise your right hand.

DR. ELIZABETH ANDERSON, DEBTOR'S WITNESS, SWORN

THE CLERK: You may be seated. Please speak into the microphone.

### DIRECT EXAMINATION

12 BY MR. BERNICK:

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Good morning, Dr. Anderson. We apologize for -- we 14∥ apologize for the delay in the elevator and then making you sit through scheduling matters, but we'll get to your testimony 16 now.

Could you tell the Court briefly what it is that you 18 are here to address this morning?

- Yes. Your Honor, I am here to address the essential 20 | question of whether exposures to Grace products have caused the diseases that the claimants have introduced.
- Okay. With that as an introduction, could you tell us a 23 little bit about your educational background and we would show 24∥ at this point Demonstrative 2264. Go ahead, Dr. Anderson.
- Yes. My academic training began at the College of William 25 A

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### Anderson - Direct

and Mary where I was a pre-med student planning to go to medical school, in my fourth year. I decided to not do that, but I had equivalent training in biology and chemistry and chose chemistry as my major. I was solicited by fellowship to go to the University of Virginia to continue in the training in organic chemistry, mechanistic organic chemistry, where I completed my Masters Degree work. And during that time I taught the pre-med sections of the laboratories in organic chemistry, and continued my academic training under a Defense Department fellowship which dictated that I do my research at a military base in concert with an academic institution. Completed by Ph.D. work in 1970.

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Thank you. The Court has heard about risk assessment 14 already in this trial and, indeed, heard very specifically from 15 Dr. Joseph Rodricks. Do you know Dr. Rodricks?

Yes. Dr. Rodricks and I were colleagues as early as the 17∥ mid-70s. He was the functional head of the risk assessment activities at the FDA, Food Drug Administration, and I was the 18 19 counterpart at EPA.

How far back, and maybe you've already identified that, 21 but how far back do you go in the field of risk assessment? 22 And I don't mean to ask embarrassing questions, but it's 23 designed to find out what the extent of your background is.

I go back to origins of the first applications of 25 risk assessment, to judgments about environmental agents,

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### Anderson - Direct

incorporating for the first time in 1975 the concepts of exposure, past, current and future exposures, to understand the potential for disease causation.

- Did your experience include a series of years spent at the EPA, the Environmental Protection Administration?
- Yes. As soon as I was released from my Defense Department 7 | fellowship obligations, I went directly to EPA in its first 8 year of operation --
- 9 | I'm going to show you --
- -- in 1971. 101

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- I'm sorry. I want to show you Demonstrative 2265 and ask 11| 12 you whether that would help you go through your activities at 13 the EPA relating to risk assessment?
- Yes. And, in the early years, I had begun working with 14 A 15 the then administrator Bill Ruckelshaus on a series of issues 16 involving carcinogens. It was a period of time in the nation's 17∥ history where there was thought to be an epidemic of cancer 18  $\parallel$  caused by environmental agents. So, the focus at EPA in 1971 was on suspect carcinogenic agents. We worked on a series of pesticides, became aware of a series of air pollutants where there were tumors in animals or humans and we had pursued a policy of zero tolerance because the application of safety factors and threshold levels for safety for carcinogens had not been accepted and the origin of that policy came from the Food, 25 Drug and Cosmetic Act, the Delaney clause, which it said if

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### Anderson - Direct

there were tumors in animals or humans there was no tolerable risk.

Trying to follow that policy at EPA had not worked and I was asked to direct the first committee to address a functional cancer policy. That was in the fall of 1975. the executive director of that committee. We reported at the first use of risk assessment and risk management that had ever been reported or adopted by any agency in the United States.

That policy called for, for the first time, if you can imagine, exposure assessment, does response modeling, in addition to what had been done in the past. The concept of evaluating how likely an agent is to be a carcinogen based on 13 human data supplemented by animal studies. These first guidelines called for a systematic approach to evaluating the weight of evidence and exposure and likelihood of risk to human populations. It also called for creating a group within the agency to carry out these responsibilities.

I founded and directed that group, it was called the Carcinogen Assessment Group and rapidly, after the success of that group, I founded the Exposure Assessment Group, the Productive Effects Group, and the expanded office for all of the risk assessment activities. I directed that office for ten years and I am co-author of EPA cancer policy with the then administrator Russell Train. It was published in the Journal of the National Cancer Institute. We performed hundreds of

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### Anderson - Direct

risk assessment. I co-authored those risk assessments during that period.

- Thank you. I want to ask you about -- turning to Demonstrative 2266. There's been a reference made, I believe, by Dr. Rodricks, concerning the red book. Could you tell us about the red book and what your involvement, if any, in the red book was?
- Yes. The EPA experience had formed a lightening rod for discussions about using dose response extrapolations, exposure assessment and estimation of risk for public policy decisions. It was one of the major, I would say, stimulus, for the convening of the National Academy's Committee to address the appropriateness of these policies, could risk assessment and 14 risk management work on a broader basis, and by that time my 15 group at EPA had published more than 150 risk assessments. 16 we were very far down the road. This committee and this publication, to which I was an advisor and visited many times because our work was one of the cornerstones of their 19 deliberations, is the landmark book that's established the paradigm for risk assessment. It's cited all the time, cited by parties and interested organizations all over the world and in many subsequent National Academy documents.
- Thank you. Turning to Demonstrative 2006, which is also a demonstrative that we used in connection with Dr. Rodricks 25∥ testimony, could you tell us briefly how it is that the science

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### Anderson - Direct

of risk assessment has evolved, particularly in the last two or three decades?

A Yes, I can. I often think of risk assessment as originating with Koch's principles. These principles sought to answer questions of causation for infectious disease, isolating the organism from the host, cultivating the organism and then reinserting it in the host and if the host responded to the original disease, causation was established.

Also, going on pre-1964, in the public health regulatory communities were these simplistic safety factor approaches that established no observed effect levels or other means of establishing a level that was regarded as safe and in the scientific community, there were early observational studies we call case reports in epidemiology that addressed the results that some medical doctors had diagnosed in their patients, certain diseases that might be associated with occupational exposures.

By 1964, we were seeing several different things happening. One of the critical events in 1964 was the publication of the Bradford Hill criteria which for the first time gave a real structure to what was expected of epidemiology studies if they were going to establish causality between the agent and the disease and these principles addressed consistency across the studies, the temporal issues and other issues.

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### Anderson - Direct

These principles promptly became useful, as I understand, to the interface of judicial use, which is not my field, but I understand that structure was useful. But they were useful in other ways, because they stimulated the conduct of structured epidemiology studies. So, studies became more structured, they became more useful in many different ways. Of course, human data still remain the best source of information. But following the regulatory approach of what I call the Public Health Agency approach, during the 70s is just what I've discussed. We've encountered the situation with suspect carcinogens and the rejection by the scientific community of just willy-nilly applying safety factors. And so the quantitative based risk assessment process was established. 14∥But, here were see a divergence between what Public Health 15∥ Agencies were doing to carry out their missions to be preemptive and protective and what was really called for in establishing causality. So, it's been an interesting period and interesting that I've been able to participate in a good deal of it. Well, let's talk a little bit about that divergence. know we're going to return to it later, but since you've mentioned it, what exactly was the divergence that you just

referred to that began to evolve in the 1970s?

The process of risk assessment that was defined by EPA in 1975 simply sought to answer two questions. How likely

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### Anderson - Direct

is an agent to cause disease or if a disease is already caused, what is the dose that -- what is the circumstance that might have caused the disease or if a disease is -- if a dose is current, would you expect that there might be impacts on populations in the future.

In that case, the Public Health Agencies essentially have to fill data gaps and the red book that I mentioned earlier details those gaps and calls them inference judgments. So when, for example, the EPA did their risk assessments when I was there, we followed guidelines and said where the science stops we will fill the gaps with very precautionary assumptions. So, we were seeking to establish plausible upper 13|| bounds on risk, recognizing that the risk could be considerably less, even approaching zero, but to make decisions to preempt and protect the public. It's a very different process from establishing causality which is -- as I understand, causality needs to be science based and not inference judgment based. Okay. And I know that we're going to return to that. Turning to slide, or Demonstrative 2267, have you been involved in developing literature in the field of risk assessment? Yes, I have. I have published, I have participated in founding the leading society in risk assessment. I served as its president from 1984 to 1985. I have held other posts in that society, but I think the most exciting one has been as editor and chief of the journal, Risk Analysis and

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<u>International Journal</u> which I think is undeniably the leading journal in the field of risk assessment.

It has a world-wide circulation of 4,000. It goes to about 80 countries and its board and its editorial staff are made up of scientists from the academic communities, governmental bodies, and international representatives in the private sector. It is ranked high in the impact factor and it's also ranked very high in the social science citation index. We've been as high as number two of 65 journals, I believe, within the last six years and as high as number four, more recently listed in the Interdisciplinary and Mathematics citation index.

MR. BERNICK: Your Honor, at this time, we would proffer Dr. Anderson as an expert in the field of the risk assessment of toxic agents or potentially toxic and toxic agents, including specifically asbestos.

MR. MULLADY: Brief voir dire, Your Honor?

THE COURT: Yes.

VOIR DIRE EXAMINATION

20 BY MR. MULLADY:

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- Q Good morning, Dr. Anderson.
- 22 A Good morning.
- 23 Q Your doctoral degree is in organic chemistry, is that 24 correct?
- 25 A Yes. Mechanistic organic chemistry.

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## Anderson - Voir Dire/Mullady

Your expertise in risk assessment, as I understand it from your CV, has been in the context of regulatory and legal matters, is that right?

I think it's in the scientific context of evaluating multi-disciplinary information to address issues of how likely an agent is to cause disease, to address issues of dose response characteristics; that is, at what level could that disease occur and then to address issues of exposure and then to wed the two, to address the essential questions of how likely is there to be an association between that exposure and disease.

May I see 433 please? Exhibit 433 on the screen here is a 13∥ copy of your CV which I believe you appended to one of your 14 expert reports in this case. And I was reading from the second 15 sentence in the first paragraph which says, "She specializes," 16∥ referring to you, "in risk assessment as a basis for addressing the complex problems that arise in the context of regulatory and legal matters, related to health and the environment for national, international companies and governments." Is that accurate?

MR. BERNICK: Your Honor, I don't believe that's proper impeachment.

THE COURT: I --

MR. BERNICK: There's nothing that's inconsistent about that.

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## Anderson - Voir Dire/Mullady

THE COURT: This witness can answer the question if it's coming from hers. I'm not sure it's inconsistent, but I'm sure the witness can answer this question.

- Q Is that an accurate statement of your credentials, ma'am?
- A Well, I don't think any single declarative sentence can accurately reflect my credentials. I think this sentence reflects some of what I've done.
- 8 Q Now, you have no formal medical training, is that right, 9 ma'am?
- 10 A I have not been to medical school, if that's what you're 11 asking me. No.
- 12 Q Yes. You also have no legal training, correct?
- 13 A Correct.

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- 14 Q And you're not an industrial hygienist, right?
- 15 A I am not an industrial hygienist.
- 16 Q And you're not a bio-statistician, correct?
- 17 A I've had courses in statistics. I have used statistics in 18 my work, but I would not say I'm a bio-statistician.
- 19 Q Okay. And as I understand it, none of the risk
- 20 assessments that you've done, that have dealt with asbestos,
- 21 have been published in a peer-reviewed journal, is that right?
- 22 A That's wrong.
- 23 Q That's wrong? What risk assessments on asbestos that 24 you've done have been published in peer-reviewed journals?
- 25 A Risk assessment has many steps. I would say the work that

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Anderson - Voir Dire/Mullady

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I did at EPA passes more scrutiny than the several -- in our journal we have three to four peer reviewers. So the work I did at EPA was certainly carefully scrutinized. I did the risk assessment work on the first issue of Ingestion of Asbestos  $5\parallel$  over a period of time in the 70s, from '73 to '78, to determine whether or not amosite from reserved mining might be a causative agent of any health issues for people who consumed 8 the water from Lake Superior.

In 1978, I was co-author of the first risk assessment 10 work for EPA's air programs. In 1980 -- late 84, I believe, is 11 the date, I was responsible for commissioning the work with Dr. 12 Nicholson to do the cancer chapter for the 1986 publication of 13 EPA's risk assessment.

MR. MULLADY: Excuse me, Your Honor, but --

THE WITNESS: I'm getting there.

MR. MULLADY: Excuse me, ma'am. I believe the question, Your Honor, was very simply, have any of her risk assessments been published in a peer-reviewed journal.

I'm getting there. I said these --

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- Well, that was the question.
- -- these risk assessments that I'm a part of received far 21 | A 22 more scrutiny than just a risk assessment journal. So, to 23 dismiss them is not appropriate. But in my resume', you will 24 see that I published one of the earliest papers, if not the earliest papers, inspecting a part of the risk assessment

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Anderson - Voir Dire/Mullady process which is the proposed six different mechanisms of action, very critical to both the hazard identification and to exposure and dose response.

Later, within the next year, I published comparative risk assessment investigating the risk associated with asbestos in place and asbestos removal. So, it was a comparative risk assessment. So, those two --

- And what peer-reviewed journal was that published in, ma'am?
- 101 Α Pardon. Yes --
- MR. BERNICK: Excuse me. 11
- 12 No --

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It's on my resume'. 13 | A

MR. BERNICK: Excuse me. She said she can answer the 15 guestion. She's already given you two examples, we're now onto the third. If you want to ask what journal it's been published in, Your Honor, she can -- that's a follow up question. He shouldn't be interrupting the witness.

THE COURT: I think you did ask, so I think she should be entitled to answer the question.

- I'm sorry, ma'am, have you finished your answer?
- I was just citing these publications. They're on my 23 resume' and they were peer-reviewed journals and they were some 24 of the first work done in risk assessment on asbestos, both on 25 mechanisms of action, one of the very important questions to

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# Anderson - Voir Dire/Mullady

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risk assessment, and one on full comparative risk assessments in particular circumstances on asbestos exposures and disease.

- I asked you the same -- well, my partner, Garret Rasmussen or Mr. Slocum, I can't remember which, asked you this same  $5\parallel$  question at your deposition. Can we take a look at Pages 27 to 28, please. Let's go back up a little bit further in the text.
  - I was speaking to the EPA risk assessments.

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- Excuse me, ma'am, I haven't asked you a question yet.
- That they were not published -- well, you put this in 10 front of me.

I'm about to ask you a question and then I'll be happy to 12 | listen to your answer. At deposition, were asked the following 13 | question; "Do any of your publications attempt to assess 14 whether exposure to asbestos caused an individual's illness?" 15 And your answer was; "I have worked with asbestos and risk 16 assessment since the earliest days at EPA starting in the 17∥1970s. One does not generally publish a risk assessment and I don't think I have attempted to publish any of my risk 19 assessments that have dealt with asbestos." I'm sorry, the question was -- and let's go further in, so we see the full context here. The question is a publication that addresses 22 whether exposure to asbestos caused an individual's illness as 23 ppposed to assessments of the risk to a general population. And you asked, "When you say published, what do you mean?" And, the question was; "Well, let's start out, published in a

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Anderson - Voir Dire/Mullady 47 peer-reviewed journal?" And your answer was; "No, I don't think I have published any of my risk assessments in a peer-reviewed journal. All of my risk assessments address risk 3 | to individuals as well as risk most all, risk to individuals as 5 well as a risk to populations." Was that the testimony that you gave in deposition, ma'am? Yes, and he was asking me about the EPA risk assessments 71 and I was explaining that those risk assessments normally are 9 not published in peer-reviewed journals. Today I'm saying, 10|| those risk assessments are under more scrutiny than articles in 11 peer-reviewed journals because they are read by so many different parties and scrutinized by so many scientists. 13 Thank you, ma'am. And, he had my resume', so he certainly knew my 15 publications otherwise. 16 MR. MULLADY: I think we understand your answer. Thank you, ma'am. No objection to the proffer. 17 MR. BERNICK: Nate? I take it from Mr. Finch's 18 shaking his head that you don't -- the ACC does not have an 19 objection. 20 MR. FINCH: No, objection to the proffer. 21 MR. BERNICK: Thank you. 22 THE COURT: All right. The witness may express an 23 24 expert opinion as proffered. 25 CONTINUED DIRECT EXAMINATION

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BY MR. BERNICK:

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Dr. Anderson, could you just tell us -- and we're going to get right to the risk assessment that we're going to be talking about in this case here, on the very next questions -- but could you just tell us what the basic elements of a risk assessment are as a general matter, and I'd like to show Demonstrative 2268.

I think as I said earlier, the first question is, Yes. can an agent cause disease and, of course, we know asbestos in certain situations considering fiber size and type, can absolutely cause disease. The dose response assessment is the next critical step, that's been discussed, I think here. 13 | Exposure assessment is then the evaluation of the cumulative 14 | exposure that individuals and populations receive and the 15 fourth step is the characterization, wedding all the previous 16 three steps together to address the essential question and in this case, are exposures to Grace product groups responsible for claimants' disease.

Thank you. Now, we've already heard from Dr. Lees. Did 20 | he participate in the risk assessment that was associated, or that's been done for Grace in this case? 21

22 Yes, he did.

Okay. And just indicate for the Court where you're going 23 0 24 generally, what role, if any, did you play, what was the nature 25 of your role in connection with the risk assessment that was

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done for purposes of this case?

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My role, I suppose is, I integrated the information from the first part of exposure assessment, the concentration data from the industrial hygiene studies I received from Dr. Lees. I added the frequency and duration portions of the exposure assessment to arrive at a cumulative exposure. Dr. Moolgavkar has discussed, I believe the dose response characteristics for asbestos and has identified certain levels that I've called benchmarks, so I could have the benchmarks for the risk characterization. I have then gone forward to evaluate the cumulative exposures for groupings, we call nature of exposure groups, and then compared their exposures to Dr. Moolgavkar's benchmarks. 13 |

I have then organized the outcome of that comparison 15 to pass that outcome on for the next analysis which I understand is Dr. Florence's analysis.

Thank you. I want to show you what we have as a demonstrative, and we've put it in the form of a big magnetic board, Your Honor, we will also tender the demonstrative as a slide or a smaller version of this after it's completed, as 2296, for its files.

UNIDENTIFIED MALE SPEAKER: What was the number for that, Dave?

MR. BERNICK: 2296.

25 But, Dr. Anderson, looking to the portion of 2296 that's Q

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displayed on the magnetic board, does this show the sequence of, or the different steps of the risk assessment that you participated in, in connection with this case?

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Yes, it does. As I said, the concentration information for the exposed claimants' groupings was provided, analyzed and provided to me by Dr. Lees. I performed the -- I completed the exposure assessment by using his concentration values. I added the exposure frequency and duration to arrive at cumulative exposures of dose and then I compared those cumulative exposures of dose to benchmarks from Dr. Moolgavkar's work and from the literature that he used to define benchmarks for comparison.

Okay. This formula that appears at the top of 2296, 14 concentration times exposure frequency times duration equals 15 dose, and then to proceed to look at dose response and then to 16∥risk, is that a sequence and a formula that is unique to this case?

No, it is not. This has been the sequence and formula, if 18 A 19|| you will, that has been consistently used since the origins of 20 | risk assessment in my background since 1976, codified in the 21 four steps by the National Academy in 1983.

Okay. Let's begin with the first part of that formula, 23 which is dose, the calculation of dose. Turning to Exhibit 2270, could you explain for us the central question that was addressed in the risk assessment for this case, as concerns the

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calculation of dose?

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The central question is how our accepted methods, used to calculate the doses resulting from exposure to Grace products and the ingredients of that analysis are listed here, 5 the concentration multiplied by the frequency, by the duration of exposures, provide the cumulative exposure for the individual or the claimant group.

Okay. Now, we've already heard from Dr. Lees but I want

to talk first of all about the concentration part of it and ask 10 $\parallel$  you just to give the Court an overview of what it is that Dr. 11 Lees did as you understood it, in order to provide a foundation 12∥ for how it is that you then pick up from his work and what you did with it. So could you just give the Court a very brief 14∥ overview of your understanding of what it is that Dr. Lees did? Well, Dr. Less did several things. The first thing he did is, he defined or he flushed out the exposure definitions for the nature of exposure Categories A through E.

Okay. Let's show 2269 and I want to ask you whether 2269 19 $\parallel$  reflects the basic categories that Dr. Lees worked with?

It does and the Category A is the category of individuals 20 | A 21 who mixed Grace products. Category B, category of individuals who were in areas to exercise their trade by removing or 23∥ cutting Grace products. The C category is the category of individuals involved in installing Grace products. D is a 25 person at a site where these products were being used, but they

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were not in the room with, they were out of the line of sight, most likely with the products in it. Category E would be an individual in the space when the products were being either applied or sprayed.

- Now, in this chart it emphasizes that these are all job activities that were analyzed as concerns Grace products. For purposes of the work, the risk assessment that was done in this case, did you or others working with you analyze the exposures that the claimants had with respect to -- or industrial hygiene data that was available with respect to job activities relating to non-Grace products?
- No. We did not have information relating to non-Grace 12 13 products. So, we were focused on what exposure did these particular claimants have from Grace products, per se.
- Okay. Now, as an example, Dr. Lees talked about the fact 16 that when it came to the personal installation we have a person who is spraying, what kind of product that Grace was being analyzed when it came to the asbestos containing mixture being sprayed from a hose?
- Grace had fireproofing products that were being sprayed 20 and I understand from Dr. Lees that they were using a wet 21 method of application for their products.
- That's exactly what I was going to get to. In connection with the work that was done to do the risk assessment in this 25 case, did you all focus not on the wet application -- not only

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on the wet application pertaining to Grace product, but did you also analyze dry applications of other kinds of products?

- Dr. Lees is aware of the differences between the dry applications which were not Grace products as I understand it, and the wet application of Grace products. We also analyzed -or he analyzed the exposure data and we used that to analyze further through the exposure duration and frequency the exposures to individuals who were painting on or troweling on Grace products.
- Okay. But when you carried through the industrial hygiene 10 data, was that the data that related to the wet application or 11 the dry application done by others?
- 13 His work was related to the Grace installation per se. The wet application.
  - Okay. Now, what kinds of values, what kinds of values did Dr. Lees calculate after having reviewed the industrial hygiene data with respect to these different job activities? What kind of calculations did he do?
- Well, he first of all defined the exposure for the categories. He gathered the data, he qualified the data and he provided his time weighted average mean concentrations by two analyses. One was what he called a stratified analysis where he took each study and averaged the study to get the mean of the study and he averaged them across the studies and the other 25 was what is, I think he referred to as a meta analysis when he

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averaged all the values across all the studies. So, he provided all of this to me.

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- Okay. Now, you just reused the word "mean", in talking about a mean concentration, and mean also appears on the overall exhibit, which is 2269. Let's deal with this question of the mean concentration. Tell us whether or not industrial hygiene data that is generally available in risk assessment, 8 tell us whether or not industrial hygiene data reflects to 9 varying degrees, variability, variability.
- Well, certainly it does because industrial hygienists 11 collect their data on different days and different places when 12∥ environmental factors are changing, and there are variations in 13∥ those factors. There will be some other variations in 14 collection methods and analytical methods and even in the way 15 some individuals work with the products.
  - Showing you 2271, does this capture some of the reasons why or the drivers for variations, and what kinds of effects they can have on concentration values?
    - MR. MULLADY: Objection, leading.
    - MR. BERNICK: That's fine.
  - Could you explain, please, Dr. Anderson, what it is that Exhibit 2271, the demonstrative, reflects as concerns variation?
    - MR. MULLADY: Objection, leading.
  - THE COURT: No, it is not leading. Explain what the

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It is leading. If anything. You can correct slide reflects. the statement, thank you, not leading.

Go ahead, Dr. Anderson.

THE COURT: You can answer.

THE WITNESS: May I?

THE COURT: Yes, please.

Go ahead.

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Well, I think the question is, why is that variation measured data, and we've always dealt with this. We dealt with this very overtly at EPA in the early years when we were trying to measure for the first time environmental data and use it for exposure assessment. We quickly found that we had variation in 13∥ sample technique, analytical technique, different people may apply or do something as a receptor that's different from another person, and we found that environmental variables were very essential. Which way the wind is blowing and where the samples are taken, with respect to humidity, and open windows. It's very difficult to get just samples that are not widely influenced by these factors.

At the end of the day, I know that Dr. Lees has stated that the environmental variables predominate by far. From my experience I would agree with him, that's what I've seen in the data that I've seen collected over the last 30 years.

Now, Exhibit 2269 reflects that in the work that was done

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on concentration, the concentration data -- and I think you've indicated the same thing -- focused on -- a mean was calculated for the concentration data, is that accurate?

That is accurate.

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Okay. Now, tell us why it is that the mean is something that is of value, or that is the step that we're talking about here, in the risk assessment, tell us why it is that the mean is used.

Well, the mean is used and has been used, as I said, for 10∥ the last 30 years as the predominate way to capture 11 concentration in a risk assessment and that is because over a long period of time, and that is for long term exposures, over 13 a long period of time, with the predominance of environmental factors, they will cancel out. If a person is doing the same 15 | activity repeatedly, always a receptor and the same location repeatedly, the variables and the environmental data will cancel out and the person will be exposed over a long period of time to that mean value. So, that's why we've always used the mean value for those kinds of analysis.

Let's take a case where we have a factory that's emitting 21 a certain material of interest and we want to know what kind of concentration for that material exists right at the border of the factory, right at the fence line. Could you give me an example of a factor that would produce variability in the 25 results, but would tend to cancel out over time?

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- Wind. Α 1
- 2 Q I'm sorry?
- Wind. 3 Α
- Explain for us why it is that wind is one of those 4 variables. 5
  - Well, wind patterns are definable variables and over time, if we have a monitor at a fence line and we have variable data over a long enough period of time, all those variable in the wind pattern, will be captured.
- 10 Q Okay.

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- And that is why long term monitoring for air, for example, 11|| A 12 is encouraged over short term monitoring.
- Okay. And if the wind pattern tends to predominate; that 13 14 | is, that overwhelmingly it's always in one direction, what 15 | happens to that fact as time evolves? What happens --
- THE COURT: I'm sorry, would you restate that? 16
- If there's a predominating direction for the wind, how 18 does that emerge over the long term?
- Well, the concentration data that are collected will 19| 20 | eventually come to a mean concentration that will reflect the 21 predominance of that wind pattern. But in different times and different days, that's going to change.
- I want you to look at 2272 and we can show it on the 24 screen and ask whether this would assist you in explaining what 25 you've just described regarding variability and a mean over the

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long term, would that help you describe that to the Court?

Objection, foundation. Your Honor, I MR. MULLADY: think with this witness we haven't yet heard that she created these slides and that they would assist her in her testimony.

MR. BERNICK: Well, I just asked her the latter and it's irrelevant whether she created the slides. You can cover that on cross examination. The foundation is whether it would assist the Court.

THE COURT: I think that is the foundation question, whether it would assist, and that is the question he just posed to the witness. So, I need an answer to that question before I can rule on the -- before there is an objection. You may answer.

THE WITNESS: All right. What we see here is --

MR. BERNICK: No, no, no.

THE COURT: Answer yes, or no. Whether it will assist you.

Mr. Mullady is raising issues about the admissibility of your testimony, so I want to just ask you, tell us whether this demonstrative would assist you in explaining to the Court your testimony regarding the mean?

I believe it will.

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MR. BERNICK: Okay. And could you -- Your Honor, may I have the witness address the Demonstrative 2272 for the 25 Court?

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THE COURT: Yes.

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MR. BERNICK: Thank you.

Go ahead, Dr. Anderson.

I think what this helps us do is, we see on the 5 | left-hand side the exposure variability. If we were thinking 6 of that monitor at the fence line, we will see some days lower 7 exposures, some days a higher exposure and in the short term, 8 we see quidance from EPA that says, you can't really use those 9 data to characterize long term. And if we're dealing with 10∥ short term risk assessments, we sometimes, depending on the 11 circumstance, use our professional judgment as to whether we 12 have to reflect that variation in short term cases, whether 13 it's acute or whether it's short term meaning very few events 14 over a long period of time.

But as we go across the bottom to the long term, what 16 we find is that those variable converge to the mean, that that 17 receptor, staying there long enough is the constant. So that receptor will get over time that mean concentration.

I want to stop you right now and just focus on what you've just said. This receptor; that is, the person whose exposure you're measuring, is a constant. Tell us what you mean when you say that person as a receptor is a constant over the long term.

If that receptor is in a particular place, doing a 25∥ particular activity with respect to a product, or living in a

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particular place with respect to a source, a factory, they
become a constant because they capture, they don't change what
they're doing, what changes around them that influences the
variability, the overwhelming variability, are these
environmental factors that cancel out as the person stays there
a long time.

- Q What have you indicated -- first let me just ask you, in order to satisfy Mr. Mullady, did you or did you not participate in the creation of this slide?
- 10 A Yes, I did.

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- 11 Q What about the word "receptor", was that your word or 12 somebody else's word?
- 13 A That's my word.
- Q Okay. What about the word "mean", was that your word or somebody else's word?
- 16 A That is my word.
- Q What about all the words on this slide, are they your words or somebody else's words?
- 19 A Those are my words.
- Q Okay. Now, what is indicated at the right-hand side when you talk about the use of the product, the composition of the product and the proximity up to the product?
- 23 A Very specific to the evaluation in this case, we have the use of the product, meaning the person who is spraying, or the person who is mixing, or the bottom individuals and the

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categories that are bystanders to other applications, we have them at a proximity to the product application. These become constant factors. The composition of the product is going to also be a constant factor as we take the exposures from that as the source, as if it were the factory.

- That's fine. Now, on the basis of this, could you tell me, this analysis that you've gone through, do you have experience and familiarity with what the -- well, let me take -- let me strike that and go back. You've said that the EPA has now been involved in risk assessment for more than 30 years?
- Starting in 1976.
- Okay. And you've said that at the EPA you've participated 13 | Q in literally hundreds of risk assessments?
- Yes, I did. 15 Α

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- Okay. Tell us whether the EPA, whether you're familiar 16 17∥ with what the EPA has said by way of guidance on this very 18 subject?
- Well, the guidance on this subject comes from the logic 20∥ behind what I just discussed and the guidance consistently says 21 that the mean is the appropriate value to use when assessing 22 concentrations at the maximum exposed point under the Clean Air Act. It says the mean is the appropriate concentration for evaluating site wide data when an individual has potential to 25∥ be exposed to variable data over that site. The mean

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concentration is used in EPA's pesticide programs for the same reasons, for the application and use of pesticides. We see this use of the mean based on the logic I just described, and it's prevalent in EPA guidance.

Showing you 2217, are there particular documents that have reflected the EPA's guidance?

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- Yes, there are. I think this is just one of many excerpts. Here we see from the 1992 risk assessment guidance for superfund sites, the average concentration is most representative of the concentration that would be contacted at a site over time. On the right-hand column we see that in the 12 EPA 1986 risk assessment, that the average concentrations were 13 used from the epidemiology studies in order to construct what is still used -- this is the document I spoke of earlier -what is still used by EPA as the dose response characterization for asbestos.
  - Thank you. Showing you 2274, could you explain how this bears upon the same subject?
- There has been -- this is a directive from the 20 deputy administrator of EPA that was issued in 1992, warning 21 against the overuse of maximums and suggesting that leaving 22 | values at their mean is more appropriate. Because if we maximize everything we vastly -- we create a community of numbers that have no relevance to the populations and that's 25 essentially what this is saying.

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I'll take you back to 2272 for a moment, if we could do that, PJ. What if you had a -- I believe what you've done here is a risk assessment that is -- or reconstructing as the risk assessment relating to long term exposures?

Yes. Α

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What if you had a totally different mission in this case, what if your mission in this case was not to talk about risk over the long term, but to talk about risk for somebody who had only very sporadic exposure to the product, would you follow the same approach?

No, if they're over or under these either short-term 12∥ exposures or a few short-term events, I would probably express 13 both an average concentration and a maximum concentration, 14 because they're still on this left-hand part of the curve. 15 They have not had time enough to converge to the exposure of 16 the mean concentration.

- I'm showing you 2273. Does this relate to the same 18 subject?
- 19 A Yes.
- And could you just give a short explanation of how 2273 20 Q 21 bears upon your testimony in this case?
- Well, it's a demonstration of what we've been discussing. 22 A 23 In this particular case we're not talking about the short-term 24 exposures on the left. The concentration and duration factors 25 have been set to very long-term maximums, so the risk

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assessment is dealing with -- the risk assessment exposure work is dealing with chronic exposure, and the only appropriate metric is the average concentration.

Why is it that you focused on long-term exposure? That is 5 to say -- we're going to talk about what you've done with duration and cumulative exposure. Why is it that you keep on  $7 \parallel$  focusing on the long-term? What is that -- what, if any, relationship does that have to the kind of dose that you're calculating?

In this particular case I thought it important to set up a 11 maximum screen. Not to try to come to realistic factors, but 12 that's essentially the first question. If we assume maximums; 13 that is, not just EPA's Exposure Factors Handbook maximum --14 | recommended maximum of 25 years for an occupation but 45. 15 we assume constant exposure over a full day, every day, eight 16 | hours a day for that 45 occupational lifetime, we're talking about 11,250 days or 90,000 hours of exposure. So we are clearly as far out on the long-term exposure curve as we can get with any reasonable -- unreasonable, actually, assignment of occupational exposures.

Go back to 2272 for a moment. If we now assume that the long-term is 45 years, is there any sense from your point of 23∥ view in assuming that for 45 years a person was constantly -- a constant person at the site was constantly exposed to the 25 maximal wind pattern, maximal exposure circumstance that might

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exist from time to time. Is there any merit to that kind of approach?

- A I think it's inconceivable that that person could be at the wrong place at the wrong time all of the time for 45 years.
- Q So let's take, for example, wind. If the wind is in the direction such that say from the spray -- the spray is always in -- is in your face, would that be on a given day?
- 8 A Yes.

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- 9 Q Would that be the high concentration or the low 10 concentration?
- 11 A That would be the high concentration.
- 12 Q Is there any sense in assuming that wherever that person 13 is for 45 years the wind is kind of following them around, so 14 it's always in their face?
- 15 A No.
- 16 Q Let's show 2275 to get to the point at which you enter
  17 into this process. We have Dr. Lees, who has the product
  18 descriptions, the definitions, and gives you the mean
  19 concentrations. What is it that you decided to do with the
  20 mean concentrations?
- A Yes, for each of the nature of exposure categories defined on the left-hand side that we discussed earlier, I selected the highest mean value from Dr. Lees' analysis to assign to each of those categories for each product type.
- 25 Q Thank you. And do we now -- are we now in the position --

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we're taking off the magnet boards. We see a summary of what was done when it comes to concentration; that is, that we had Categories A through E that Dr. Lee defined them, that Dr. Lee gave you the mean concentrations, and then again what is it that you did with the mean concentrations, which one did you use to choose -- did you choose to use?

I chose to use the highest, because he presented two means of evaluating his data. I chose the highest from whichever the data set was.

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- Thank you. Let's talk about frequency and duration. Could you just describe in general terms what now -- how now 12∥ the risk assessment proceeds, what the next steps are in 13 general terms, and then we'll focus on how you implemented 14 | those stages?
- 15 A Yes. To get to the cumulative exposure assessment I 16 needed to take his maximum concentrations and then ask the 17∥ question how much frequency of exposure would an individual in these categories get and over what time period. So those were the next two steps in my analysis.
  - Okay. Could you just describe in your own words -- well, let me just put it this way. Tell us whether there was a specific analysis that was done in order to provide the factual predicate for your calculations.
- Well, I did several levels of analysis. Initially, I 24 25 thought it would be very important to really characterize how

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often a Grace product might be in a building that a person would contact or how often events might occur, or, in fact, how many buildings actually have these kinds of products. And for the bi-standard categories, the D's and E's, how often would they -- if they are visiting a site, how often are they likely to overlap with an exposure circumstance at a site, and I did those analyses, and they're reported in my report.

But, eventually, I decided that the most important thing in this analysis is to make this a very conservative screening analysis, meaning if I set all the parameters very high, I could be very certain that there would be a low probability that anybody would be exposed to anything any high than those values. So I have chosen in the screening analysis that I have really used this final set of assumptions.

Let's focus, first of all, on exposures to different kinds I'm going to show you 2276 and ask you whether of products. this accurately summarizes the work that people working for you did in order to analyze what products were available to the marketplace over time; that is, what Grace products were available over time to the marketplace.

Yes, this is a display. If we look down the left-hand side, we see the Grace product types, the vermiculite-only 23 products, then the next category of vermiculite with chrysotile 24 added, then the category of chrysotile-only products, and then 25 combined post-construction. What the bars going across show is

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the lifetime of those products in commerce, and what we did with these data was to choose for any one year the maximum concentration that any one in any of the nature of exposure categories could've had to any of these products.

In other words, that person had a choice of getting the highest exposure to any one of these products in that year, and here I have chosen to illustrate that with the max to a D exposure -- Category D in 1953 from acoustical plaster. That turned out in 1953 to be the highest exposure for a mean TWA 10|| value used over the period of 250 days in the year for that 11 person in D exposure category.

- So the analysis that you've just talked about, you get the 13 products out there in use over time, you then figure out the maximum by year. Am I right from what you just said --
- 15 Α Yes.

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- -- that this is done not for all categories together but for each category separately? 17||
- 18 l Α Correct.
- 191 Okay. Now, what was the next step? After you've done 20 that with the products, what was the next step?
- The next step was to incrementally take 45-year rolling 22 | blocks of exposure starting in 1920 when the first products 23 | appeared and to calculate for each of the A, B, C, and D categories blocks of 45 years of exposure that had three maximums. We maximized in the beginning the mean highest

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concentration. We allow that person to be exposed to any one of the products in a single year that had the highest concentration for that year, and we maximized that concentration for all days in that year. Then we had the rolling block of 45 years going forward through 2007, and then we chose the highest one of those 45-year blocks to characterize the exposure to that exposure -- nature of exposure category individual group.

I'm showing you 2277. Does that chart summarize the data that was used in the application of the parameters that you just described?

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- Yes, it does. It shows at the top the historical data of 12 13∥ when the products were on the market. Next it shows an illustration of the 45-year going forward blocks; 1920, 1965, 1921, 1966. The last block of years going out in the analysis, 15 16| 1963 to 2007. So we have a cumulative exposure here of 100 percent of the time for frequency for every person for 250 days 17 -- occupational days in a year for a 45-year life span to not only the highest mean concentration, but the highest mean 191 concentration to any product in the year. 20
- I'm showing you 2278. Does this now reflect the inputs to the does calculation formula that you used; that is, which 23 concentrations were selected, which frequency of exposure was selected, and which duration was selected?
- 25 A Yes, it does. The frequency was set to 100 percent for

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every day, 250 days per year. I've already discussed the concentration. And the duration was set to an occupational extreme upper bound of 45 years to the highest exposure product for each year within the 45-year block, and then we chose the maximum of the 45-year blocks to characterize the group. 5

- And I want to talk about conservatism; that is, you said that you wanted to take a conservative approach. Have you -do we have a series of slides that go through the different respects in which this approach is conservative?
- (No verbal response from the witness.) 101
- 11 You have to respond.
- 12 | A I'm sorry. I didn't hear you.
- I said, do you have a series of slides that explain the 13 | Q 14 different respects in which this approach that you took was 15 conservative?
- 16 A Yes, I do.

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- Okay. For purposes of kind of keeping the Court 17 Q 18∥ remembering the part of this slide that matters, we have for frequency exposure 100 percent and for duration 45 years, 19∥ highest exposure product for each year, and the maximum of any 45-year period. Those -- that's the -- those are the 21 22 parameters that you've chosen?
- 23 | Yes. Α
- I'm showing you Slide 2279. Could you explain how -- is 24 25 this one of the slides that relates to the conservatism of your

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approach?

A Yes.

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- Q Could you explain to the Court how this slide relates to the conservatism of your approach?
  - A Yes. In -- on the right-hand side just thinking now of the frequency duration assumption wetted, we have 90,000 hours for the individual claimants for exposure to Grace products.
- 8 Q Now, where did that 90,000 come from? This is Category B?
- 9 A This is Category B, but we used it for everybody.
- 10 Q Okay.
- A So we're taking Category B as an illustration and one sub-group of occupational individuals in Category B would be in the custodial maintenance trade. In earlier work we've done using data from the literature we find estimates of the hours that custodial workers actually contact asbestos-containing materials in buildings, and that number is 8,100. And for the same kind of workers coming in contact with VAI attic insulation, we find that number is 692. So in a very careful analysis of how much contact there would actually be, we see that by choosing for screening purposes the 90,000 hours for this particular example, we have been extremely conservative and have set a very high screen.
- 23 Q Now for the Court's benefit, V refers to vermiculite?
- 24 A That's right.
- 25 Q Well, we've referred obviously to Zonolite. So it's ZAI

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and VAI are the same thing?

Yes.

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Okay. Now, let's turn to Slide 2280, and on 2280 in order to talk about conservatism we've included 100 percent and 45 years as the reminders of the approach that you used?

That's right.

Could you explain what information you have, if any, as reflected on this chart that reflects the conservatism of those benchmarks; that is, 100 percent for 45 years?

Well, yes. Again for the exposure frequency in earlier work we find the building maintenance worker actually is in contact with the ACM material 16 percent of the time, for attic insulation, VAI, Zonolite, 1 percent of the time. And also an analysis we did in one of our early -- one of the earlier analysis I mentioned before, is we found that if we used published data, that the trawled-on and sprayed-on products for those product categories, even if we assumed that all trawled-on/sprayed-on products were Grace products, which they're not, would be in only 20 percent of the buildings.

So here all of this cancels that, because we have assumed 100 percent exposure. So every building -- every time one of these maintenance workers goes to a building, it is a 23 building with Grace products, not the 20 percent, and they're 24 not spending 1 percent of the time, they're spending 100 25 percent of the time, eight hours a day, five days a week, in

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contact with the source of exposure depending on their labor category.

- Q What about the 45 years, what, if any, comparisons did you do in order to analyze the conservatism of the 45-year parameter?
- A Yes, I mentioned earlier that EPA's guidance in the
  Exposure Factors Handbook is for a maximum of 25 years, and
  it's interesting when -- and I think we will discuss this
  later, but when I reviewed -- our team reviewed the information
  from the PIQs, we found that for those who reported the time
  periods, the duration, we found that 100 percent were under 50
  years, 98 percent under 45 years, and interestingly enough, 54
  percent, the EPA number, under 25 years, and 27 percent under
  10 years. So this means that there's every indication that
  we're vastly overestimating, and intentionally so, because we
  set it up as a very conservative screen, the cumulative
  exposures for individuals in these nature of exposure
  categories.
- 19 Q Now, this is for the A and C categories?
- 20 A That's for A and C.

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- Q And when you say 27 percent under 10 years, was that under 10 years of exposure to a Grace product or under 10 years of exposure to all asbestos products?
- 24 A It was under 10 years of exposure to Grace products.
- 25 Q Okay. Now, incidentally --

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1 A Well --

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THE COURT: Oh, wait. Pardon me. I'm sorry. I misunderstood. Just a minute until I correct my note, please.

(Pause)

THE COURT: Okay. Thank you.

- A I should add that in the review of the questionnaires we accepted if someone self-identified as an AC, that they were exposed to the Grace product. And so, yes, we are assuming that they're exposed to Grace products in the PIQ review.
- 10 Q Okay. But, do you actually know whether they were exposed to Grace products alone or other products?
- 12 A No.
- 13 Q Okay.
- 14 A No.
- 15 Q Now, do you have one more slide that related to the conservatism analysis?
- 17 MR. BERNICK: Can we show the Court 2281?
- 18 Q Could you explain how this slide relates to conservatism?
- A Well, first of all, as I've said, we don't give these
  claimants any time to do anything else but be exposed to Grace
- products, because this a full working lifetime of 11,250 days, 22 90,000 hours, and yet we know they had other exposures, which I
- 23 can talk about later.
- Secondly, we -- if we worked with any non-Grace
  product or non-exposed to a Grace product, of course, they had

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no time to have that exposure, because they're -- all of they're exposure time has been consumed. And if they worked less than the 11,250 days, of course, their exposures would decline. And we've seen the less-than hours in an earlier exhibit.

- So put simply, you've assumed 45 years, eight hours a day exposure to Grace product. If it turns out that they worked 8 with other products, then what effect, if any, would that have on -- what would that tell you about the duration that you've 10 assumed and the dose that results from it?
- If they worked with other Grace products, of course, 11 A 12 then --
- 13 Q But not -- of a non --

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- I mean other non-Grace product -- sorry -- in other 15 occupations. Then -- or if they worked in other occupations 16 and had no other exposure, the number of hours would go down, therefore, the cumulative exposure concentrations that have been presented in this analysis would be lessened accordingly.
- On the basis of all the work that was then done with the 20 | approaches you've described to the Court, did you, in fact, come up with a maximum cumulative exposure for each of the different categories?
- 23 A Yes, I did.
- I want to show you Exhibit 2282 and have you explain that 24 25 to the Court.

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Objection, Your Honor. This data is MR. FINCH: based on the PCM/PCME conversations. I'm going to object on lack of foundation and hearsay grounds.

MR. MULLADY: Join

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THE COURT: Mr. Bernick.

MR. BERNICK: Well, I'll respond to that as follows. First of all, this witness has testified that she took the mean concentration calculations from Dr. Lees and used those for purposes of her analysis. She has not expressed an opinion that is the same or different from Dr. Lees' opinion. Your Honor resolved that issue in connection with Dr. Lees' opinion and overruled it.

So all of the -- for them to come out and say, oh, 14∥ well, this witness here, who hasn't even expressed an opinion 15∥ on the matter, is using Dr. Lees' data is now subject to an objection that you previously overruled with respect to Dr. Lees, I don't understand where that comes from. So they can make the objection, but it's already been overruled, and I'm 19∥ not going to go back over each element of Dr. Lees' analysis 20∥ with this witness she's relying on. Now, I can bring that out 21 if you'd like.

MR. FINCH: Your Honor, I stand on the objection even 23 though the prior objection is overruled. I believe that's in error. To protect my client's interest and their rights, I 25 stand on the objection that any testimony from this witness

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that is based on Dr. Lees' estimates, which in turn are based on the PCM to PCME conversions are, (a) objectionable, because neither Ms. Anderson nor Dr. Lees with an S has the expertise or the foundation to make those conversions, and secondly that they're hearsay. That's the basis of the objection. understand the Court has overruled the objection with respect to Dr. Lees with an S, but I need to preserve the objection with respect to this witness as well.

MR. MULLADY: Joined by the FCR.

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MR. BERNICK: Your Honor, I -- not only did Your 11 Honor overrule it, you overruled it after Dr. Lees with an S testified very specifically about how the conversion was done, and that he not only participated in the conversion, but they're making something sound like a big deal that's a piece 15∥ of arithmetic. But be that as it may, if their purpose is to preserve their record as having made the objection, I don't have any problem with that, but --

THE COURT: All right. The -- I think the objections 19 | have a different purpose. With respect to Dr. Lees, Dr. Lees testified that he participated in designing what the conversion was about and for, and I think the objection is different with respect to that. The objection as to this witness using that data I think is objectionable for a different reason. But I think at this point in time the objection's also going to be overruled.

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I'm going to take a look at all of this when I get all of the evidence into the case and analyze at that point in time how it all goes. But nonetheless, for now we're going to finish this trial with all the witnesses here, so that in the event that I do at some point have to reconsider any of this, I've at least got the evidence on the record.

So that you understand, I do not believe that I'm going to reverse this decision when I see all the evidence, but nonetheless, for now it's overruled. And in the event that I think I'm wrong when I do have all the evidence, I will on my 11 own reconsider whether it's appropriate. So it's overruled.

MR. BERNICK: Let me just ask, so that I'm sure that 13 my record is also good down the road.

14 BY MR. BERNICK:

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Dr. Anderson, tell us whether or not you relied upon the 15 Q 16 concentrations determined -- the concentration calculations determined by Dr. Lees.

Yes, I relied on the concentration values that he 19∥ provided, and, in fact, one can't really proceed with a risk assessment in any other way. If we look at the guidance that's in the IRIS database at EPA, it cautions against not making corrections. So while I wouldn't make them myself, I don't proceed with an asbestos-type risk assessment, unless this factor has been taken into account by someone qualified to do that work.

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Is it customary for you in your field of expertise of risk assessment to -- strike that. Is the kind of information -the information that you got from Dr. Lees regarding concentration calculations including an adjustment for PCM and PCME, is that the kind of information that is reliable -considered to be reliable by people like yourself in the field of risk assessment?

- Α Yes, it is.
- Okay, and in Dr. Lees' case do you have any issue in your mind whatsoever concerning the qualifications and expertise of Dr. Lees to perform the mean concentration determinations?
- 12 Α No.

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- 13 | Q Do you have any issue about the propriety of his decision 14 to in-turn rely upon a person who is expert in materials fiber 15 analysis who actually go look in the microscope once, go look 16 in the microscope twice to make the calculation?
- This is routine -- routinely done in the world of risk 17 assessment for asbestos.
- Thank you. Now I'd like to turn to Exhibit 2282 and have 19 20∥ you explain to the Court what it is that Exhibit 2282 reflects.
- These are the resulting screening values that we have been 22 | speaking of presented here for screening purposes for each of 23 the nature of exposure categories, with emphasis on the fact 24 that they are very high screens, meaning very, very 25∥ conservative screens, and at the bottom of this slide there's

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the repetition of the frequency and duration assumptions.

- Let me just ask, does Exhibit 2282 accurately summarize the data that you have generated regarding the cumulative doses for each of the categories there displayed, A through --
- Yes, it does. 5 A
  - Does this then bring us to the conclusion of the work on your risk assessment up through dose?
- 8 A Yes.

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- Okay, and do we now see in Exhibit 2296 a summary of the work that has taken place that brings you to the different doses that we have as displayed under the first column? 11
- 12 Yes, it does.
  - MR. BERNICK: Now, Your Honor, I have I think probably about 15 minutes left in the direct examination. can complete it, or if Your Honor would feel more comfortable taking a morning break, either way is fine.

THE COURT: Isn't it only eleven o'clock?

MR. BERNICK: Yes.

THE COURT: You want to take a recess?

MR. BERNICK: I don't want to take a recess. I'm 20 prepared to go -- take it to the end, but I just --21

I think -- why don't you finish, and then THE COURT: we'll take a short recess and let the -- we'll take a recess before cross.

> MR. BERNICK: Okay. Fine.

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BY MR. BERNICK:

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What is the next step in the analysis, the risk assessment analysis?

Well, of course, it's the risk characterization question of what do these mean. Do these -- what do these mean in terms of the nature of exposure categories of claimants as far as answering that initial question that I proposed? Did they get their illness from exposure to a Grace product?

I'm showing you 2283. Could you explain exactly why the issue is framed in the way or question is framed in the way reflected on 2283?

Yes, and the question really is exactly this question, what does science say about the significance of doses resulting from exposure to Grace products.

In order to answer that question, I see that the next step is reflected in 2269. Just to compare the doses to these benchmarks, could you describe in your own terms what is involved in that exercise?

Yes, as I spoke of earlier, we spoke of the Koch principles. We spoke of the world of epidemiology and dose response, and I know that this Court has heard from Dr. 22∥ Moolgavkar who works in this particular field, and the concept of having now these cumulative exposures and asking this 23 essential question really is what does it mean in terms of 25 disease causation or these high levels, low levels, how can we

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compare them to some benchmarks that might give us guidance as to their significance.

What benchmarks did you use?

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- I used benchmarks from Dr. Moolgavkar's analysis, and I 4 think I emphasized in my deposition that I have the utmost confidence in Dr. Moolgavkar, but there's a long history here. There's a longer history than just his opinions, because this 8 work has been evolving over many, many years, and his work is the essential work that brings all of this literature together, but we find a great deal of support in the literature for his 11 work.
- 12 Have you offered an independent opinion with respect to 13∥ the epidemiology, or are you relying upon Dr. Moolgavkar's 14 work?
- I'm relying on Dr. Moolgavkar's work. 15
- 16 I'm showing you 2262. Is this --
- MR. BERNICK: I believe, Your Honor, it may actually 18 already be in evidence under a different number.
- But are these the benchmarks -- from what Dr. Moolgavkar, 19 20 but are these the benchmarks that you used in the course of 21 your analysis?
  - Yes, they are.
- Okay. Now, Dr. Moolgavkar talked about the fact that 23 24 there were not reliable data -- observational data that was 25 | gathered below 15 -- a burden of 15 fibers per mil per year.

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Are you familiar with the 15 fiber per mil -- fiber per mil per year concept?

- 3 A Yes, I am.
- Q Okay, and he then further observed that once you get below 15, you're in, therefore, a range of the unobserved, and then below 2.8, which came from the auto workers study or the auto mechanics study, you were in a range of risk, in a sense, affirmatively not being seen. Now, I don't want to ask you about the details of those different numbers. I simply want to ask you are you familiar with those basic concepts? That is a range of observed data -- reliably-observed data, a range where there isn't reliable observational data, and then an area where there is reliable observational data, but it doesn't show a risk.
- 15 A Yes, I am, and we have spoken of this concept since 1976.
- 16 Q I want to show --
- 17 A The range of observation --
- 18 Q Wait. Let me interrupt you for just a second --
- 19 A Yes.
- 20 Q -- and just put on the board 2284, which I believe already
  21 has been used by Dr. Moolgavkar, but I'm -- my focus with you
  22 is to simply have you, as you were beginning to say, provide
  23 the historical regulatory perspective. That's what I want you
  24 to comment on, is the regulatory side of what is illustrated in
  25 that chart.

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A Yes, I spoke earlier on the earlier slide of the divergence between evidence of causality and evidence that is a preemptive public health policy-based approach. And here the first one of these curves was drawn when I was at EPA in 1976. Conceptually, we see with agents an observed range from human studies, sometimes only animal studies, but the important thing is as we leave that range of observation, we regard that range as science based.

As we go downward, EPA to this day -- and we created this curve in 1976 as a means of establishing a plausible upper bound on the risk, meaning the real risk could be less even approaching zero, and we put that label on every document that we wrote at EPA when I was there. And I think the other important thing is I've observed the use of this generic approach by the National Academy of Sciences and the Institute of Medicine. I was familiar with and commented on some of their work, and an example of that work is the Gulf War veterans study where they actually made distinctions about establishing causality from exposure for those individuals and chose to use only the observed range for that work.

- Q Thank you. And that gets back to the difference between science --
- 23 A That's right.

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- 24 Q -- and the regulatory guidance or rule?
- 25  $\parallel$  A That's right, and the inference judgments that I used to

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